NOVARTIS AG
Form 6-K
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 or 15d-16 OF

THE SECURITIES EXCHANGE ACT OF 1934

Report on Form 6-K dated September 17, 2009

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F: x Form 40-F: o

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Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: o **No**: x

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- Investor Relations Release -

Novartis receives FDA approval for Valturna®, a single-pill combination of valsartan and aliskiren, to treat high blood pressure

- *Valturna combines in a single pill valsartan, an angiotensin receptor blocker, with aliskiren, the only approved direct renin inhibitor*

- *Valturna is the first therapy to target two points within the renin angiotensin aldosterone system (RAAS), which plays a key role in regulating blood pressure*

- *Valturna offers significantly greater blood pressure reduction than either valsartan or aliskiren alone(1)*

Basel, September 17, 2009 The US Food and Drug Administration (FDA) has approved Valturna® (aliskiren and valsartan) tablets, the first and only medicine to target two key points within the renin system, also known as the renin angiotensin aldosterone system (RAAS), an important regulator of blood pressure(2). This is the first approval for Valturna, which is indicated for the treatment of high blood pressure in patients not adequately controlled on aliskiren or angiotensin receptor blocker (ARB) monotherapy and as initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals(1).

This unique combination brings together the powerful blood pressure lowering effects of valsartan and aliskiren, said Joe Jimenez, CEO of the Novartis Pharmaceuticals Division. It offers an important additional treatment option for physicians and hypertension patients, many of whom are not at their blood pressure goal. Valturna builds upon our strong cardiovascular franchise and is consistent with our long-term commitment to developing effective and innovative therapies. It further strengthens our growing portfolio of single-pill combinations to treat high blood pressure.

Valturna combines in a single pill valsartan, the active ingredient in Diovan®, the number one selling blood pressure medication worldwide(3), and aliskiren, the active ingredient in Tekturna®, the only approved direct renin inhibitor (DRI). Valturna offers significantly greater blood pressure reduction than either valsartan or aliskiren alone(1).

When it comes to diagnosing and treating high blood pressure, there is a real need for innovative therapies that help patients get to a healthier blood pressure range, said John Flack, M.D., Valturna investigator, and Chairman of the Department of Internal Medicine, Wayne State University, Detroit. Now for the first time, we have a treatment option in one pill that targets two key points of the RAAS, which may be overactive in many hypertensive patients.

This approval was primarily based on a pivotal eight-week randomized, double-blind, placebo-controlled clinical trial in approximately 1,800 patients, which studied aliskiren 150 mg and 300 mg and valsartan 160 mg and 320 mg alone and in combination. The initial doses of aliskiren and valsartan were 150 mg and 160 mg, respectively, and were increased at four weeks to 300 mg

and 320 mg, respectively. Blood pressure reductions with the aliskiren/valsartan combination were significantly greater than with the monotherapies or placebo at the 8-week primary endpoint. Mean systolic and diastolic blood pressure reductions from baseline were 17.2/12.2 mmHg for aliskiren 300 mg/valsartan 320 mg, compared with 12.8/9.7 mmHg for valsartan 320 mg, 13.0/9.0 mmHg for aliskiren 300 mg, and 4.6/4.1 mmHg for placebo ($p<0.05$ for aliskiren/valsartan vs monotherapies or placebo).

The single-pill combination Valturna targets the RAAS in two ways. Valsartan blocks, at the receptor level, the action of angiotensin II, a component of the RAAS that causes blood vessels to tighten and narrow. Aliskiren directly inhibits renin, an enzyme produced by the kidneys that starts a process that leads to formation of angiotensin II. An overactive RAAS may contribute to high blood pressure. By targeting two key points within the RAAS, Valturna helps blood vessels relax and widen so blood pressure is lowered.

Research suggests that up to 85% of patients with high blood pressure may need multiple medications to help control their blood pressure(4),(5) underscoring the need for effective combination treatments.

High blood pressure affects over one billion individuals globally(6),(7) and is a major risk factor for cardiovascular disease, the number one leading cause of death worldwide(8). If left untreated, patients with high blood pressure are at risk of cardiovascular events such as stroke, heart attack and heart failure, and of organ damage including kidney failure and vision problems(6). Up to 65% of patients with high blood pressure do not have the condition under control(9).

About Diovan

The number one selling blood pressure medication worldwide(3) and one of the fastest-growing high blood pressure drugs on the market today, Diovan is available as a powerful first-line treatment for high blood pressure in more than 90 countries and in more than 65 countries for the treatment of heart failure in patients who also take usual therapy including diuretics, digitalis and either beta blockers or ACE inhibitors, but not both. In the US and Switzerland, among other countries, Diovan is indicated for the treatment of heart failure in patients who cannot tolerate ACE inhibitors. Diovan is also indicated in more than 50 countries to treat patients who have survived a heart attack.

About Tekturna

Tekturna, a direct renin-inhibitor, is the only drug that works by directly targeting renin to decrease the activity of the RAAS(10). Renin is an enzyme produced by the kidneys that starts a process that narrows blood vessels and, when inappropriately activated, may lead to high blood pressure. Tekturna reduces plasma renin activity and helps blood vessels relax and widen so blood pressure is lowered.

The heart and kidney protection potential of Rasilez/Tekturna, in addition to its blood pressure lowering ability, is currently being investigated further in the landmark ASPIRE HIGHER program, the largest ongoing cardio-renal outcomes program worldwide involving more than 35,000 patients in 14 trials.

Rasilez/Tekturna is approved in over 70 countries. Tekturna was approved in the US in March 2007 and in the European Union in August 2007 under the trade name Rasilez. In July 2009, Rasilez also received approval in Japan. Tekturna HCT, the first single-pill combination involving Tekturna, was approved in the US in January 2008 for second-line treatment of high blood pressure, and more recently for first-line use. The single-pill combination Rasilez HCT was approved in the European Union in January 2009. Other single-pill combinations with Rasilez are currently in development including a single pill combination with amlodipine.

Novartis is focused on improving the lives of the hundreds of thousands of people with cardiovascular and metabolic diseases. As a global leader in cardiovascular and metabolic health for nearly 50 years, Novartis provides innovative therapies and support programs to treat high blood pressure and diabetes both major public health issues. The portfolio includes the number one selling blood pressure medication worldwide, the first and only approved direct renin inhibitor, a single pill combining two leading high blood pressure medicines, and a DPP-4 inhibitor.

Valturna is available in two strengths as tablets containing aliskiren and valsartan: 150 mg/160 mg and 300 mg/320 mg.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as commitment, may, risk, potential, or similar expressions, or by express or implied discussions regarding potential additional marketing approvals for Valturna, potential new indications or labeling for Tekturna, or regarding potential future revenues from Valturna, Tekturna or Diovan. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Valturna will be approved for sale in any additional markets. Nor can there be any guarantee that Tekturna will be approved for any additional indications or labeling in any market. Neither can there be any guarantee that Valturna, Tekturna or Diovan will achieve any particular levels of revenue in the future. In particular, management s expectations regarding these products could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; government, industry and general public pricing pressures; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; the impact that the foregoing factors could have on the values attributed to the Novartis Group s assets and liabilities as recorded in the Group s consolidated balance sheet, and other risks and factors referred to in Novartis AG s current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in each of these areas. In 2008, the Group s continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 99,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Novartis AG

Date: September 17, 2009	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting